K003479

JAN 1 8 2001

2.4 510(k) Summary and 510(k) Summary Certification

510(k) Summary

U-Systems Ultrasound System
U-Systems INC.
Prepared November 1, 2000

Product Name: USI-2000 Diagnostic Ultrasound System

Manufacturer: U-Systems Inc.

Generic Name: Diagnostic Ultrasound System

Classification Name: Ultrasound Imaging System and Transducers (Class II); Classification codes:
IYO 892.1560 System, Imaging Pulsed Echo, Ultrasonic
IYN 892.1550 System, Imaging, Pulsed Doppler, Ultrasonic
ITX 892.1570 Transducer, Ultrasonic, Diagnostic

Contact Person: Sheila W. Pickering Ph.D.
2081 Longden Circle
Los Altos, California 94024
Telephone/Fax 650 969 6114

A. Legally Marketed Predicate Device
The U-Systems device is substantially equivalent to the following predicate devices with regard to device features, specifications, and intended use.

Sponsor	Predicate Device
Acoustic Imaging, Inc.	AI 5200
Diasonics, Inc.	Gateway Series

B. Device Description
The USI-2000 Ultrasound System is a general purpose, mobile, software controlled, diagnostic ultrasound system. It function is to acquire ultrasound data and display the data in B-Mode, M-Mode, Color-Flow Doppler, Pulsed Doppler and Power Doppler (also known as Amplitude Doppler), or a combination of these modes. The system currently includes 2 transducers, the L7 and L10 for use in 1) Abdominal and other and 2) Peripheral Vascular.applications.

C. Intended Use
The USI-2000 is a general purpose ultrasound imaging instrument intended for use in the evaluation of soft tissue and vascular tissue in the abdomen, small organs, musculo-skeletal (conventional) and peripheral vascular system. It consists of the main ultrasound unit and transducers designed for various applications.

Diagnostic Ultrasound Indications for Use

510(k) Number(s): N/A

Device Name: USI-2000
Diagnostic Ultrasound Pulsed Echo System
Diagnostic Ultrasound Pulsed Doppler Imaging System

Intended Use:

Clinical Application	Mode of Operation									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (specify)*	Other (specify)
Ophthalmic										
Fetal										
Abdominal		N	N	N		N	N		Note 1	
Intraoperative (specify)										
Intraoperative Neurological										
Pediatric										
Small Organ (breast, thyroid, testes)		N	N	N		N	N		Note 1	
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
Tranesophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Laproscopic										
Peripheral Vascular		N	N	N		N	N		Note 1	
Musculo-skeletal Conventional		N	N	N		N	N		Note 1	
Musculo-skeletal Superficial										

Note 1: Combined includes: B/M; B/PWD; B/Color Doppler; B/Amplitude Doppler; B/Color Doppler/PWD and B/Amplitude Doppler/PWD

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D. Substantial Equivalence

The USI-2000 is substantially equivalent to the currently marketed predicate devices. It has the same technological characteristics, is comparable in key safety and effectiveness features, uses the same basic design, construction, and materials, and has the same intended uses, operating modes and transducers.

E. Performance Data

The device has been evaluated for acoustic output, biocompatibility and thermal, electrical and mechanical safety and has been found to conform with applicable medical device safety standards.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 1 8 2001

Sheila W. Pickering, Ph.D.
Regulatory Affairs Consultant
U-Systems, Inc.
2081 Longden Circle
Los Altos, California 94024

Re: K003479
USI-2000 Diagnostic Ultrasound System
Regulatory Class: II
Product Code: 90 IYN/21 CFR 892.1550 and 90 IYO 21 CFR 892.1560
Dated: November 6, 2000
Received: November 9, 2000

Dear Dr. Pickering:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

This determination of substantial equivalence applies to the following transducers intended for use with the U-Systems Ultrasound System USI-2000, as described in your premarket notification:

Transducer Model Number

L7 (7.5 MHz)
L10(10 MHz)

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval) it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic QS inspections, the FDA will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, the Food and Drug Administration (FDA) may publish further announcements concerning your device in the Federal Register. *Please note*: this response to your premarket notification does not affect any obligation you may have under sections 531 and 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This determination of substantial equivalence is granted on the condition that prior to shipping the first device, you submit a postclearance special report. This report should contain complete information, including acoustic output measurements based on production line devices, requested in Appendix G, (enclosed) of the Center's September 30, 1997 "Information for Manufacturers Seeking Marketing Clearance of Diagnostic Ultrasound Systems and Transducers." If the special report is incomplete or contains unacceptable values (e.g., acoustic output greater than approved levels), then the 510(k) clearance may not apply to the production units which as a result may be considered adulterated or misbranded.

The special report should reference the manufacturer's 510(k) number. It should be clearly and prominently marked "ADD-TO-FILE" and should be submitted in duplicate to:

Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center (HFZ-401)
9200 Corporate Boulevard
Rockville, Maryland 20850

This letter will allow you to begin marketing your device as described in your premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus permits your device to proceed to market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4591. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or at (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

If you have any questions regarding the content of this letter, please contact Rodrigo C. Perez at (301) 594-1212.

Sincerely yours,

for Daniel G. Schultz, M.D.
Captain, USPHS
Acting Director, Division of Reproductive,
Abdominal and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosures

Diagnostic Ultrasound Indications for Use

510(k) Number(s): N/A

Device Name: USI-2000
Diagnostic Ultrasound Pulsed Echo System
Diagnostic Ultrasound Pulsed Doppler Imaging System

Intended Use:

Clinical Application	Mode of Operation									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (specify)*	Other (specify)
Ophthalmic										
Fetal										
Abdominal		N	N	N		N	N		Note 1	
Intraoperative (specify)										
Intraoperative Neurological										
Pediatric										
Small Organ (breast, thyroid, testes)		N	N	N		N	N		Note 1	
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
Tranesophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Laproscopic										
Peripheral Vascular		N	N	N		N	N		Note 1	
Musculo-skeletal Conventional		N	N	N		N	N		Note 1	
Musculo-skeletal Superficial										

Note 1: Combined includes: B/M; B/PWD; B/Color Doppler; B/Amplitude Doppler; B/Color Doppler/PWD and B/Amplitude Doppler/PWD

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K003479

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Diagnostic Ultrasound Indications for Use

510(k) Number: N/A

Device Name: 7.5 MHz Transducer
Diagnostic Ultrasound Transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (specify)*	Other (specify)
Ophthalmic										
Fetal										
Abdominal		N	N	N		N	N		Note 1	
Intraoperative (specify)										
Intraoperative Neurological										
Pediatric										
Small Organ (breast, thyroid, testes)		N	N	N		N	N		Note 1	
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
Tranesophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Laproscopic										
Peripheral Vascular		N	N	N		N	N		Note 1	
Musculo-skeletal Conventional		N	N	N		N	N		Note 1	
Musculo-skeletal Superficial										

Note 1: Combined includes: B/M; B/PWD; B/Color Doppler; B/Amplitude Doppler; B/Color Doppler/PWD and B/Amplitude Doppler/PWD

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Diagnostic Ultrasound Indications for Use

510(k) Number: N/A

Device Name: 10 MHz Transducer
Diagnostic Ultrasound Transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (specify)*	Other (specify)
Ophthalmic										
Fetal										
Abdominal		N	N	N		N	N		Note 1	
Intraoperative (specify)										
Intraoperative Neurological										
Pediatric										
Small Organ (breast, thyroid, testes)		N	N	N		N	N		Note 1	
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
Tranesophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Laproscopic										
Peripheral Vascular		N	N	N		N	N		Note 1	
Musculo-skeletal Conventional		N	N	N		N	N		Note 1	
Musculo-skeletal Superficial										

Note 1: Combined includes: B/M; B/PWD; B/Color Doppler; B/Amplitude Doppler; B/Color Doppler/PWD and B/Amplitude Doppler/PWD

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